K000211

MAR 17 2000

21.0 510(K) SUMMARY

Submitter: **Jeneric/Pentron, Inc.**
Address: **53 North Plains Industrial Road**
Wallingford, Connecticut 06492
Contact Tel: 203-265-7397 X619
Contact Fax: 203-265-7662
Contact Person: Annmarie Tenero
Date Summary Prepared: February 8, 2000

Build-It FR is a fiber reinforced, dual cure post and core build-up resin composite material, used for restoring a crown or missing tooth. Build-It FR is to be used on any patient requiring restoration of a tooth and prescribed by a dentist.

We believe that Build-It FR is substantially equivalent to Pent Core Plus, K941373, a build-up resin composite used for restoring a crown or missing tooth. However, Build-It FR contains specially treated glass fibers. These fibers are the same fibers contained in Alert, K974131. The addition of the fibers in Build It FR increases the compressive strength of the core build-up.

Safety and effectiveness is not affected due to the contents of Build-It FR being the same as Pent Core Plus, K941373. Also, safety and effectiveness is not affected because the fibers that are used in Build-It FR are the same type of fibers contained in Alert, K974131. Cytotoxicity testing was not performed due to Build-It FR being substantially equivalent to Pent Core Plus, K941373. Also because Build-It FR contains the same kind of fibers that are contained in Alert, K974131.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Ms. Annmarie Tenero
Jeneric/Pentron, Incorporated
53 North Plains Industrial Road
Wallingford, Connecticut 06492

Re: K000211
Trade Name: Build-It FR
Regulatory Class: II
Product Code: EBF
Dated: January 21, 2000
Received: January 24, 2000

Dear Ms. Tenero:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000211

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K000211

DEVICE NAME: **BUILD-IT FR.**

INDICATION FOR USE: Build-It FR is a fiber reinforced, dual cure post and core build-up resin composite material that is used for restoring a crown or missing tooth structure. Build It FR is substantially equivalent to Pent Core Plus, K941373. However, specially treated glass fibers have been added to Build It FR. These fibers are the same type used in Alert, K974131. The addition of these fibers to Build It FR increases the compressive strength of the core build-up.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over –The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K000211